Exhibit 3

State of California ex. rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.

Exhibit to the Declaration of Nicholas N. Paul in Support of Plaintiffs' Motion for Summary Judgment as to Defendant Dey

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: ***State of California, ex rel. Ven-A-Care v. Abbott Laboratories, et al.*** **Case No. 03-CV-11226-PBS**	**Judge Patti B. Saris**

DEFENDANTS DEY, INC. AND DEY, L.P.'S OBJECTIONS AND RESPONSES TO THE STATE OF CALIFORNIA'S FIRST SET OF REQUESTS FOR ADMISSION

Pursuant to Rule 36 of the Federal Rules of Civil Procedure, Defendants Dey, Inc. and Dey, L.P. (hereinafter collectively referred to as "Dey") hereby assert the following objections and responses to the First Set of Requests for Admission (the "Requests") propounded by Plaintiff State of California ("California," "Plaintiff," or "the State") on May 13, 2009.

GENERAL OBJECTIONS AND RESERVATION OF RIGHTS

1. Dey provides this response without waiver or prejudice to: (a) its right, at any later time, to object, on the grounds of competency, relevancy, materiality, privilege or admissibility as evidence for any purpose, or any other ground, to the use of the responses the Requests or the subject matter thereof, in this or any other proceeding; (b) its right to object on any ground at any time to a demand for further responses to the Requests, other requests to admit, document requests, interrogatories or other discovery proceedings involving or relating to the subject matter of the Requests; or (d) its right at any time to revise, correct, add to, supplement, or clarify any of the responses contained herein.

DEY'S OBJECTIONS AND RESPONSE

In addition to Dey's General Objections, Dey objects to this request as vague and ambiguous, *inter alia*, because it contains terms and phrases that are vague, ambiguous, overly broad, or undefined, including, but not limited to "the provider," "profit," "actually pays," "formulaic payment," and "reimbursement agency."

Subject to and without waiving the foregoing general and specific objections, Dey denies the matters contained in this Request.

REQUEST NO. 11

Admit that Dey's AWPs for each of the Subject Drugs was not based on an average of any wholesale prices.

DEY'S OBJECTIONS AND RESPONSE

In addition to Dey's General Objections, Dey objects to this request as vague and ambiguous, *inter alia*, because it contains terms and phrases that are vague, ambiguous, overly broad, or undefined, including, but not limited to "average" and "wholesale prices."

Subject to and without waiving any of the foregoing general and specific objections, Dey states that, during the relevant time period, Dey's practice has been to set AWPs for its generic drugs before they are first sold and not to subsequently change that AWP. Dey understands that this is consistent with industry practice. There are some instances to the contrary depending on the market and/or other forces. Dey's AWPs for its brand name drugs at issue in this action have been set and revised as Dey's WACs have changed. Dey understands that this practice is also consistent with industry practice.

When Dey introduced a new generic drug product to the market, it set the AWP for its drug at a certain percentage below the AWP for the therapeutically-equivalent branded product. Early on in Dey's business, Ed Edelstein of First Data Bank advised Dey that, for

purposes of acceptance by the reporting services of Dey's product as a generic, the AWP for that product should be a minimum of 10% below the innovator product's AWP, and historically, Dey has observed this principle.

Moreover, starting in at least 1999, Dey sent price notification letters on a number of occasions to California Medicaid officials explaining exactly what Dey's AWP was:

> [A]s you . . . know, the [AWP] . . . listed above does not represent actual wholesale prices which will be or has been charged or paid for this product. . . . We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators.

See, e.g., DL-0050553; DEY-MDL-0105067 to 0105095; DEY-LABS-0292039 to 0295170; DEY-BO-0018938 to 0019071; DL-TX-090579 to 090619; DL-TX-00979 to 00980; DL-TX-091309 to 091345; DL-TX-091568 to 091584; DL-TX-094547 to 094660; DL-TX-096329 to 096514; DL-TX-105183 to 105185; DL-TX-162910 to 162921; and DL-TX-163769 to 163775 (price notification letters).

Dey otherwise denies the matters contained in this Request.

REQUEST NO. 12

Admit that Dey knew that the AWPs for its Subject Drugs submitted to First DataBank would be relied on by Medicaid for reimbursement.

DEY'S OBJECTIONS AND RESPONSE

In addition to Dey's General Objections, Dey objects to this request as vague and ambiguous, *inter alia*, because it contains terms and phrases that are vague, ambiguous, overly broad, or undefined, including, but not limited to "relied on" and "for reimbursement."

Subject to and without waiving the foregoing general and specific objections, Dey denies the matters contained in this Request.

REQUEST NO. 23

Admit that the Price Publications published Your prices for Your Subject Drugs.

DEY'S OBJECTIONS AND RESPONSE

In addition to Dey's General Objections, Dey objects to this request as vague and ambiguous, *inter alia*, because it contains terms and phrases that are vague, ambiguous, overly broad, or undefined, including, but not limited to "prices." Dey further objects to this Request as unduly burdensome.

Subject to and without waiving the foregoing general and specific objections, Dey denies having knowledge or information sufficient to respond to this Request.

REQUEST NO. 24

Admit that You never disclosed to Medicaid officials responsible for reimbursement for Your Subject Drugs the actual Spreads on those products.

DEY'S OBJECTIONS AND RESPONSE

In addition to Dey's General Objections, Dey objects to this request as vague and ambiguous, *inter alia*, because it contains terms and phrases that are vague, ambiguous, overly broad, or undefined, including, but not limited to "disclosed," "Medicaid officials," "responsible for reimbursement," and "actual Spreads." Dey further objects to this Request on the grounds that it improperly assumes that Dey was obligated to report "actual Spreads" or that Dey could determine the "actual Spreads."

Subject to and without waiving the foregoing general and specific objections, Dey states that it explained to California Medicaid officials exactly what Dey's AWPs represent. Starting in at least 1999, Dey informed California Medicaid officials:

> [A]s you . . . know, the [AWP] . . . listed above does not represent actual wholesale prices which will be or has been charged or paid for this product. . . . We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators.

See, e.g., DL-0050553; DEY-MDL-0105067 to 0105095; DEY-LABS-0292039 to 0295170; DEY-BO-0018938 to 0019071; DL-TX-090579 to 090619; DL-TX-00979 to 00980; DL-TX-091309 to 091345; DL-TX-091568 to 091584; DL-TX-094547 to 094660; DL-TX-096329 to 096514; DL-TX-105183 to 105185; DL-TX-162910 to 162921; and DL-TX-163769 to 163775 (price notification letters).

Similarly, Dey has explained to Medicaid officials, including officials in California's Medicaid program, exactly what Dey's WACs represent and their relationship to the final "cost" to the purchaser. Starting in at least 1999, Dey informed Medicaid officials, including California Medicaid officials:

> As you know, WAC is referred to by data reporting services and government agencies as an "estimate," and Dey believes that WAC generally means the actual invoice price charged by a pharmaceutical manufacturer to its drug wholesalers. As you also know, WAC does not include the net effect of discounts from invoice price (based on volume of purchases, speed of payment and other factors), rebates, chargebacks, administration fees and other such cost adjustments which are well-known and commonplace in the pharmaceutical industry and can affect, to a greater or lesser degree, the actual "final" cost to each purchaser. These discounts may not be determined until some months after the date of invoice. Therefore, we remind you that WAC may well not be representative of actual market costs to those entities which you are reimbursing under Medicaid.

(Letter from Robert Mozak to various state Medicaid officials, August 10, 1999, DL-0050553.) Despite these disclosures, California has never objected to the manner in which Dey set its AWPs or WACs prior to this lawsuit. Indeed, as far as Dey knows, California has never even attempted to contact Dey to discuss the manner in which it sets its AWPs or WACs.

Moreover, the existence of a "spread" between reimbursement rates based on AWP and other prices for the Dey drugs identified in the Complaint was no secret. Publicly available information demonstrates that there was a substantial spread between some of the

AWPs and WACs for these drugs. Indeed, the AWPs and WACs for these drugs were published side-by-side in the various pricing compendia referred to by Plaintiff, and the differences between the two prices – in some cases higher than 400% – were readily apparent.

In any event, the existence of a "spread" between reimbursement rates based on AWP and the prices at which all drugs, including Dey's drugs, were purchased by Medicaid providers was a matter of public record and was widely known in the industry, and was publicly acknowledged by the government since 1968.

Government reports and studies confirm that participating Medicaid states, including California, knew AWPs were only benchmark prices that did not reflect the providers' acquisition costs, including but not limited to the following:

- In 1977, HCFA told the States that "[i]n order to set estimated acquisition costs which come close to AAC [actual acquisition costs], some states, for example, begin with AWP prices but apply a percentage markdown to determine acquisition costs." HCFA Action Transmittal No. HCFA-AT-77-113 (MMB), Dec. 13, 1977, *Medicaid - Formula for Determining EAC for Drugs*, reprinted in *Medicare and Medicaid Guide* (CCH) ¶ 28,714.

- In 1984, the HHS-OIG reported that "AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, . . . rebates, or free goods that do not appear on the pharmacist's invoices," and recommended that state agencies be precluded from using an undiscounted AWP. The report found pharmacy drug purchases were made at prices averaging approximately 15.93% below AWP, with some at 42% below AWP. *Medicaid Action Transmittal No.* 84-12 at 3, 6.

- In 1989, the HHS-OIG reported: "[w]e continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or Medicare Programs. When AWP is used, we believe it should be discounted." *OIG Rep. Concerning Medicaid and Medicare Reimbursement for Drugs* at 7.

- In 1996 and 1997, the HHS-OIG publicly issued thirteen audit reports finding that AWPs significantly exceed pharmacies' acquisition costs.

- In 1997, in connection with legislative efforts to change Medicare's AWP-based reimbursement system, the Secretary of HHS testified that "the

> AWP is not the average price actually charged by wholesalers to their customers. Rather, it is a 'sticker' price set by drug manufacturers and published in several commercial catalogs." President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid and Welfare, 105th Cong. at 265 (1997).

Moreover, discovery in various litigations is now unearthing a substantial body of documents available to federal and state Medicaid agencies, including California, for many years showing that AWPs for generic drugs do not equal providers' acquisition costs. Dey refers California to the following documents**:**

DESCRIPTION	DATE
Federal Register, Wednesday, November 27, 1974, Volume 39, Number 230, Part II, containing HCFA, 45 CFR Part 250, Proposed Reimbursement of Drug Cost-Medical Assistance Program	11/74
Title IX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC); ¶128, 714	12/77
Changes to the Medicaid Prescription Drug Program Could Save Millions	09/84
Medicare and Medicaid Guide ¶ 34,157 Medicaid-Limitation on Payment for Drugs	1984
Majority Staff Report of the Special Committee on Aging US Senate: Prescription Drug Prices: Are We Getting Our Money's Worth?	1989
Office of the Inspector General ("OIG") Report Concerning Medicaid and Medicare Reimbursement for Drugs, ¶ 38,215	10/89
Comparison of Reimbursement Prices for Multiple-Source Prescription Drugs in the United States and Canada	03/91
Cost of Dialysis-Related Drugs	10/92
Physicians' Costs for Chemotherapy Drugs	11/92
Memorandum to All Associate Regional Administrators Division of Medicaid from Sally Richardson, Director of Medicaid Bureau, regarding Expiration of Pharmacy Reimbursement Moratorium-Information	08/94
Statement by Congressman Pete Stark in the House of Representatives (with proposed bill)	02/96
Medicare Payment for Nebulizer Drugs	02/96
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services	05/96
Appropriateness of Medicare Prescription Drug Allowances	05/96
Payment for Enteral Nutrition: Medicare and Other Payers	05/96
Suppliers' Acquisition Costs for Albuterol Sulfate	06/96
A Comparison of Albuterol Sulfate Prices	06/96
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Montana Department of Public	07/96

Health and Human Services	
Review of Pharmacy Acquisition Costs for Drugs reimbursed Under the Medicaid Prescription Drug Program of the Florida Agency for Health Care Administration	08/96
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the North Carolina Department of Human Services	09/96
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Delaware Department of Health and Social Services	09/96
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Virginia Department of Medical Assistance Services	11/96
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medical Prescription Drug Program of the Nebraska Department of Social Services	12/96
Review of Pharmacy Acquisition Cost for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the New Jersey Department of Human Services	12/96
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Missouri Department of Social Services	01/97
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the District of Columbia Department of Human Services	01/97
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Maryland Department of Health and Mental Hygiene	02/97
Questionable Practices Involving Nebulizer Drug Therapy	03/97
Medicare Reimbursement for Parenteral Nutrition	07/97
Medicaid Pharmacy: Actual Acquisition Cost of Generic Prescription Drug Products	08/97
Excessive Medicare Payments for Prescription Drugs	12/97
Weekly Radio Address to the Nation, 1997 WL 767416	12/97
Program Memorandum Change Request # 298	01/98
Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs	05/98
The Impact of High-Priced Generic Drugs on Medicare and Medicaid	07/98
Are Medicare Allowances for Albuterol Sulfate Reasonable?	08/98
Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs	11/98
Medicaid Pharmacy – Acquisition Cost of Brand Name Prescription Drug Products	02/99
Memorandum from June Gibbs Brown regarding Office of Inspector General's Partnership Plan – UTAH Division of Health Care Financing Reports on Medicaid Pharmacy acquisition Costs of Brand Name and	05/99

Generic Drugs	
Report to Congress, The Average Wholesale Price for Drugs Covered under Medicare, Donna Shalala	1999
Medicare Reimbursement of End State Renal Disease Drugs	06/00
Medicare Reimbursement of Albuterol	06/00
Program Memorandum, Change Request #1232	09/00
Program Memorandum, Change Request #1447	11/00
Medicare Reimbursement of Prescription Drugs	01/01
Cost Containment of Medical HIV/AIDS Expenditures	07/01
Medicaid Recovery of Pharmacy Payments for Liable Third Parties	08/01
Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products	08/01
Medicaid's Use of Revised Average Wholesale Prices	09/01
GAO Medicare Part B Drugs: Program Payments Should Reflect Market Prices	09/01
Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, Serial No. 107-65.	09/01
Testimony of William J. Scanlon entitled Program Payment Should Reflect Market Prices before the Subcommittee on Health and the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representative	09/01
Testimony of Thomas A. Scully on Medicare Payment for Drugs before the House Energy and Commerce Subcommittees on Oversight and Investigation and Health	09/01
GAO Medicare: Payment for Covered Outpatient Drugs Exceed Providers' Cost	09/01
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Washington Department of Social and Health Services	11/01
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Texas Health and Human Services Commission	11/01
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Colorado Department of Health Care Policy and Financing	11/01
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Indiana Family and Social Services Administration	12/01
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the West Virginia Health and Human Resources	12/01
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Montana Department of Public Health and Human Services	02/02
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the	03/02

Medicaid Prescription Drug Program of the Florida Agency for Health Care Administration	
Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Wisconsin Department of Health and Family Services	03/02
Testimony of Thomas A. Scully on Reimbursement & Access to Prescription Drugs under Medicare Part B	03/02
Verbatim Transcript, Senate Finance Committee Hearing on Prescription Drug Coverage	03/02
Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products	03/02
Excessive Medicare Reimbursement for Albuterol	03/02
Excessive Medicare Reimbursement for Ipratropium Bromide	03/02
Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products	09/02
Review of Medicaid Payments for Outpatient Services and Prescription Drugs Provided to Incarcerated Recipients in the State of Florida	10/02
Statement of Thomas A. Scully before the Subcommittee on Health of the House of Committee on Ways and Means, "Hearing on Medicare Payments for Currently Covered Prescription Drugs"	10/02
Transcript from Hearing before the Subcommittee on Health of the House Committee on Ways and Means, Serial 107-84	10/03
Review of West Virginia's Medicaid Drug Rebate Program	10/03
Medicare Prescription Drug, Improvement, and Modernization Act of 2003	12/03
Update: Excessive Medicare Reimbursement for Ipratropium Bromide	01/04
Update: Excessive Medicare Reimbursement for Albuterol	01/04
Omission of Drugs from the Federal Upper Limit List in 2001	02/04
Medicaid Rebates for Physician – Administered Drugs	04/04
Variation in State Medicaid Drug Prices	09/04
Applying the National Correct Coding Initiative to Medicaid Services	10/04
GAO Medicare: Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy drugs.	10/04
Addition of Qualified Drugs to the Medicaid Federal Upper Limit List	12/04
Congressional Budget Office Medicaid's Reimbursements to Pharmacies for Prescription Drugs	12/04
GAO Medicaid Drug Rebate Program Inadequate Oversight Raises Concerns about Rebates Paid to States	02/05
Congressional Budget Office Prices for Brand-Name Drugs Under Selected Federal Programs	06/05
Medicaid Drug Price Comparison: Average Sale Price to Average Wholesale Price	06/05
Medicaid Drug Price Comparison: Average Manufacturer Price to Published Prices	06/05

OIG Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices	06/05
Medicaid Reform A Preliminary Report National Governors Association	06/05
Multistate Review of Medicaid Drug Rebate Programs	07/05
GAO Price Trends Frequently Used brand and Generic Drugs from 2000 through 2004	08/05
The Medicaid Commission Report to Honorable Secretary Michael O. Leavitt, Dept. of Health and Human Service and The United States Congress	09/05
How Inflated Published Prices Affect Drugs Considered for the Federal Upper Limit List	09/05
A Comparison of Average Sales Prices to Widely Available Market Prices: Fourth Quarter 2005	06/06
Comparison of Fourth-Quarter 2005 Average Sale Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2006	07/06
GAO Medicaid Outpatient Prescription Drugs Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Cost	12/06
Congressional Budget Office: Prescription Drug Pricing in the Private Sector	01/07
Testimony of Lewis Morris before the House Oversight and Government Reform Committee, "Allegations of Waste, Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer"	02/07
Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program	06/07
Average Wholesale Price, FDB-AWP 02023	No date
First DataBank Monthly Interest, "Understanding AWP"	09/00/1991
Barron's article entitled "Hooked on Drugs: Why do Insurers Pay Such Outrageous Prices for Pharmaceuticals?"	06/10/1996
Price Alert, "Demystifying AWP?"	06/15/1991
First DataBank, Inc. Price Alert sent by Kay Morgan, "Average Wholesale Price"	03/15/2000
Website Page from First Data Bank – The Knowledge Insider – Frequently Asked Questions	08/14/2002
FDB Website, FDB-AWP 02005-02006	11/04/2002
Price Alert-Guide to AWP Pricing, FDB-AWP 13140 and 131343	12/15/2002

California Medicaid devised its reimbursement program to use the spread and used reimbursement methodologies that built in a "spread" between a provider's acquisition

costs and reimbursement amounts to serve its own needs, including ensuring that beneficiaries of the programs had adequate access to care. Indeed, California Medicaid knew of the spread between Dey's AWP and WAC, which itself was publicly disclosed in the published compendia and otherwise.

In May 2000, the state Medicaid programs, including California's Medicaid program, received average wholesale market pricing information for about 400 national drug codes compiled by the U.S. Department of Justice ("DOJ"), without reliance on published AWPs (the "DOJ Prices"). All of the states that participated in the Medicaid program were told acquisition costs may be even lower than the DOJ Prices, "because purchasers often receive further discounts, below the advertised wholesale catalog price . . . ." *Program Memorandum Intermediaries/Carriers*, Transmittal AB-00-86 (September 8, 2000).

California Medicaid and the federal government also had access to Dey's AMPs during the relevant time period. On January 1, 1991, Dey entered into a Rebate Agreement with the Secretary of HHS, who entered into the agreement on behalf of states with Medicaid programs, including California. *See* 42 U.S.C. § 1396r-8(a)(1). The Rebate Agreement requires Dey to pay rebates to the states based on the AMP and, where applicable, Best Price for its products. *See* 42 U.S.C. § 1396r- 8(b)(1)(A). Dey has paid these rebates to the States and the federal government, further lowering the costs of drugs to the Medicaid program. The Rebate Agreement requires Dey to provide to CMS, on a quarterly basis, the AMP and, where applicable, Best Price for its products that are reimbursed by Medicaid. *See* 42 U. S.C. § 1396r-8(b)(3). The federal statute and the Rebate Agreement only obligated Dey to report AMP and, where applicable, Best Price information, not AWP or WAC. Under the Rebate Agreement and

federal statute, 42 U.S.C. § 1396r-8(k)(1), Dey must include in its AMP calculation certain discounts and other price reductions which reduce the price paid for Dey's products.

CMS has calculated unit rebate amounts ("URAs") based upon the formula set forth in federal statute and the AMPs and Best Prices reported by the drug manufacturers to the Medicaid program. *See* 42 U.S.C. § 1396r-8 (c). For instance, rebates for non-innovator, multiple source drugs are equal to 11% of AMP. *See* 42 U.S.C. § 1396r- 8(c)(3)(A-B). (Prior to January 1, 1994, the rebate percentage was 10%. See 42 U.S.C. § 1396r-8(c)(3)(A-B)). CMS provides the URAs, which constitute AMP information, to the State Medicaid programs. Thus, state Medicaid officials have the necessary information to determine the AMP for each of Dey's generic products by performing a simple arithmetic calculation, *i.e.,* dividing the URA by 11%, the applicable rebate percentage for non-innovator, multiple source drugs. *See* 42 U.S.C. § 1396r-8(c)(3)(A-B).

Deirdre Duzor, the CMS Director of the Pharmacy Division for the Medicaid program, testified:

> Q: Okay. So if you had the URA and you divided by .11, that would tell you what the AMP is, right?
>
> * * *
>
> A: Yes. The AMPs have been fairly transparent for generic drugs.

Duzor Tr. 679: 12-17.

The administrators in charge of running the Medicaid program have testified that States have had access to AMPs. *See* Vladeck Tr. 461:12-15; 463:19-464:06; Scully Tr. 627:13-20. Bruce Vladeck, the Administrator of HCFA from May 1993 to September 1997 testified:

Q: So as far as you know, people within HCFA shared AMP data with state Medicaid agencies?

A: That was my understanding.

* * *

Q: So it was entirely possible -- it was entirely possible for the heads of a state Medicaid agency to look at the AMP data on AMP prices and at the same time look at data as to what they were reimbursing for those drugs. That was entirely possible. Right?

A: It's -- I don't know any reason why it wouldn't be possible.

Vladeck Tr. 461:12-15; 463:19-464:06.

Thomas Scully, the Administrator of CMS from May 2001 to December 2003 testified:

Q: Did you ever tell any state that they should calculate their reimbursement methodology for Medicaid taking into account AMP data?

A: No.

Q: Why not?

A: States have AMP data, and they have their own political calculations, and reasons for paying the rates they pay.

Scully Tr. at 627:13-20.

California set reimbursement rates with access to Dey's AMPs and the "spreads" between Dey's AWPs or WACs and AMPs. CMS approved California's reimbursement rates for the Medicaid program with full knowledge of Dey's AMPs and the "spreads" between the AWPs or WACs and AMPs.

The existence of a "spread" between reimbursement rates based on AWP and/or WAC and the prices at which Dey's drugs were purchased by Medicaid providers did not violate the law, was not misleading, and did not cause California to make excessive reimbursement

payments. California Medicaid actively decided to use a reimbursement methodology with a built-in "spread" between a provider's acquisition costs and reimbursement amounts to serve its own needs, including ensuring that beneficiaries of the programs had adequate access to care.

Participation by providers in the Medicaid program is voluntary. To ensure that beneficiaries have adequate access to medical care, the Medicaid program utilizes AWP and/or WAC as possible bases for reimbursement to provide an economic incentive for providers' participation. The Medicaid program knew that its reimbursement methodology for the ingredient portion did not approximate providers' costs to acquire the drugs, but did not change its reimbursement methodologies because, among other reasons, it had to ensure that a sufficient number of providers enrolled to ensure access to care for Medicaid beneficiaries. Additionally, federal law requires that States' Medicaid payments "are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. § 1396a(a)(30)(A).

The Medicaid program has used AWP and WAC as benchmark prices as a way of ensuring access to care for beneficiaries because the "spread" the programs built in has been intended to cover providers' costs and ensure providers receive a profit on the transactions. Reimbursement for prescription drugs is intended to cover the ingredient cost of the drug, the costs incurred by a provider in dispensing the product, and a reasonable profit to the provider. Generally, dispensing fees do not cover dispensing costs incurred by providers, much less provide a profit. As a result, the Medicaid program used, and continues to use, AWP and/or WAC as possible bases to compensate for this shortfall in dispensing fees and to ensure that providers earn a profit on Medicaid transactions.

California was free at all times to change its pharmaceutical reimbursement under its Medicaid program to a methodology that did not use AWP and/or WAC as possible bases for reimbursement and which did not include a reimbursement "spread." In addition to the published AWPs and WACs for Dey's products, the States, including California, and federal government had access to a number of other prices for Dey's products, including Federal Supply Schedule prices, AMPs, 340B prices, Department of Veterans Affairs prices, and direct contract prices with Dey or contract prices through group purchasing organization ("GPO") prices at which federal and state agencies purchased Dey drugs directly from Dey or from wholesalers. The States, including California, and federal governments could have compared the published AWPs and WACs for Dey's products with any one of these prices and used one of the lower prices in their reimbursement methodologies.

Through reimbursement methodologies that used AWP and/or WAC as possible bases for reimbursement, state Medicaid programs, including California Medicaid, knowingly have provided larger "spreads" or margins for generic drugs than for brand-name drugs in order to provide an incentive for pharmacies to dispense lower-cost generic drugs. Generic drugs are typically less costly than brand-name drugs. For example, in 1996, the HHS-OIG found that providers' acquisition costs, on average, were 18.3% below AWP for brand name drugs and 42.5% for generic drugs.

Even though a State's reimbursement for a generic drug may give a provider a larger "spread" than a reimbursement for a brand name drug, its total reimbursement payment for the generic drug will still be lower than that for a brand-name drug, thereby saving that State money. As "spreads" for generic drugs increase, the State benefits because the larger spreads increase incentives for providers to dispense generic drugs. Moreover, contrary to Plaintiffs'

claims, Dey does not benefit from increased spreads. First, drug manufacturers, like Dey, do not receive the money which comes from the spread. The so-called spread in the reimbursement payments goes to the providers. Second, if the spread for a particular generic Dey drug is getting larger, it is almost always because the AWP of the drug is remaining the same, while the actual selling price is getting lower. At the same time, Dey's costs are increasing and its margins are declining.

In addition, since as early as 1996, the OIG and GAO have published numerous reports about the prices of drugs manufactured by Dey, including:

Medicare Payments for Nebulizer Drugs	OEI-03-94-00390	February 1996
Suppliers' Acquisition Costs for Albuterol Sulfate	OEI-03-94-00393	June 1996
A Comparison of Albuterol Sulfate Prices	OEI-03-94-00392	June 1996
Questionable Practices Involving Nebulizer Drug Therapy	OEI-03-94-00391	March 1997
Excessive Medicare Payments for Prescription Drugs	OEI-03-97-00290	December 1997
Are Medicare Allowances for Albuterol Sulfate Reasonable	OEI-03-97-00292	August 1998
Medicare Reimbursement of Albuterol	OEI-03-00-00311	June 2000
Use of Revised "Inherent Reasonableness" Process Generally Appropriate	GAO Report	July 2000
Payment for Covered Outpatient Drugs Exceed Providers' Cost	GAO Report	Sept. 2001
Excessive Medicare Reimbursement for Albuterol	OEI-03-01-00410	March 2002
Excessive Medicare Reimbursement for Ipratropium Bromide	OEI-03-01-00411	March 2002
Update: Excessive Medicare Reimbursement for Albuterol	OEI-03-03-00510	January 2004
Update: Excessive Medicare Reimbursement for Ipratropium Bromide	OEI-03-03-00520	January 2004
Medicaid Pharmacy-Actual Acquisition Cost of Generic Prescription Drug Products	A-06-97-00011	August 1997
The Impact of High-Priced Generic Drugs on Medicare and Medicaid	OEI-03-97-00510	July 1998
Medicaid Pharmacy-Actual Acquisition Cost of Generic Prescription Drug Products	A-06-01-00053	March 2002

Dey also refers Plaintiffs to the testimony of CMS and OIG officials taken in the *United States ex. rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 06-CV-11337-PBS, pending before the United States District Court for the District of Massachusetts.

Contrary to Plaintiffs' allegations, reimbursement payments made by the California Medicaid programs were often not based on published AWPs for Dey's drugs, and thus, the so-called spread was irrelevant. For example, the California Medicaid program may reimburse providers at the lowest of numerous numbers, including but not limited to: (a) a drug's Federal Upper Limit ("FUL"), a maximum reimbursement rate for a drug set by the federal government; (b) Maximum Allowable Cost ("MAC"), a maximum reimbursement rate for a drug set by California Medicaid; (c) the Medicaid provider's usual and customary charge to the general public; or (d) AWP minus a discount. Therefore, when reimbursements for Dey's drugs were based on published AWPs corresponding to Dey's drugs, the payments were less than a number of possible prices, including the provider's usual and customary charge, which is a market price charged to the general public, and the MAC price set by California Medicaid.

As the Medicaid claims data will confirm, prices charged in market transactions by providers, wholesalers and others exceed the AWPs and WACs of generic products, including Dey's products.

Dey further states that, upon information and belief, Medicaid officials entered into provider agreements which allowed them to obtain pricing information from providers from which Medicaid officials could determine "spreads." Dey otherwise denies the matters contained in this Request.